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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/807,974  | 03/24/2004  | Charles C. Hart      | A-3124-AL           | 6970             |
| 21378 7590 07/08/2008<br>APPLIED MEDICAL RESOURCES CORPORATION<br>22872 Avenida Empresa<br>Rancho Santa Margarita, CA 92688 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| MEHTA, BHISMA   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3767  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/807,974

**Applicant(s)**

HART ET AL.

**Examiner**

BHISMA MEHTA

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 10-19, 27-33 and 39-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 20-26 and 34-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 3/24/2004, 9/22/2005
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, Species A, Sub-species P, and Sub-species T in the reply filed on April 16 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 10-19, 27-33, and 39-72 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, species, and sub-species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 16 2008. It should be noted that newly filed claims 53-72 are withdrawn as being drawn to a non-elected species as the device having a seal at the distal end of the tubular member where the seal is sized and configured to form a seal with an instrument when an instrument is in place within the working channel of the tubular member and to form a zero seal when no instrument is in place within the working channel of the tubular member is not shown in the elected species (Species A – Figure 6-10). Specifically, it is not disclosed or shown that the seal of the elected species is sized and configured to form a seal with an instrument when an instrument is in place within the working channel of the tubular member.

### ***Drawings***

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the

description: 130a, 130b, 132, and 440. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 2, 12, 30, 210, 220, 252, 255, 109, 142, 362, 365, 376, 400, 461, 480, 415, 412, 118, 119, 391, 391b, 134, 135, 602, 622, 670, 650, 680, 630, 710, and 712. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be

notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

5. The disclosure is objected to because of the following informalities: In lines 20 of page 13, there appears to be a grammatical error in the phrase "the inside diameter of the access diameter 100 itself". Reference character 140 is used for a first seal in line 3 of page 13 and for a second seal in lines 6-7 of page 14. Reference character 120 is used for a second seal in line 4 of page 13 and for a first seal in lines 6-7 of page 14.

Appropriate correction is required.

### ***Claim Objections***

6. Claims 23, 25, 26, 37, and 38 are objected to because of the following informalities: In claim 23, it is unclear if the proximal end is referring to the proximal end of the elongate tubular member or the proximal end of the elongate shaft. Similarly, it is unclear if the distal end in claims 25 and 26 is referring to the distal end of the elongate tubular member or the distal end of the elongate shaft. Claim 37 recites the limitations "the occlusive lip portions" in lines 1-2 and "the seal" in lines 2-3. There is insufficient antecedent basis for these limitations in the claim. It is unclear which seal is being referred to by "the seal" in lines 2-3 of claim 37.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-9, 20-26, and 34-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear how the zero seal of Species A can float with the septum seal relative to the tubular member as the specification fails to disclose the properties of the zero seal that will allow the zero seal to float with the septum seal relative to the tubular member.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 36, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-9, 20-24, and 34-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Lafontaine (U.S. Patent No. 6,520,939). Lafontaine disclose a surgical access device having an elongate tubular member (110), a septum seal (140) formed at the distal end of the tubular member, and a zero seal (130) disposed at the distal end of the tubular member and distal to the septum seal. The zero seal is coupled to the septum seal and has properties to float with the septum seal relative to the tubular member. As to claim 2, see lines 5-20 of column 3. As to claims 3 and 4, the zero seal is a duckbill seal with an intersecting sealing portion (134A) or a double duckbill seal with two or more intersecting sealing portions (134B). As to claims 5 and 6, see Figure 3. As to claims 7-9, see lines 6-22 of column 4. The device also has a placement device (14, 40, 50). As to claim 21, the placement device is an obturator. As to claim 22, the placement device includes an elongate shaft with a proximal end, a mid-portion, and a distal end. As to claim 23, the proximal end of the placement device has a handle and the mid-portion has a reduced profile (see Figure 1). As to claim 34, the seal has opposing lip portions (132) separated by a slit portion. As to claims 35 and 36, see lines 31-46 of column 4. As to claims 37 and 38, the lip portions are capable of allowing a

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surgical item such as a surgical suture to extend through the slit portion without disrupting the seal.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Green et al (U.S. Patent 6,497,716). Lafontaine discloses the device substantially as claimed. However, Lafontaine is silent on the specifics of the distal end of the placement device being shaped like an hourglass or comprising a tapered, cone-shaped member. Green et al disclose a placement device (22) which is used to place an access device (14) where the distal end of the placement device is shaped like an hourglass and has a tapered, cone-shaped member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the placement device of Lafontaine with the placement device of Green et al as both Lafontaine and Green et al disclose surgical access devices and placement devices for placing the access devices and Green et al disclose that it is well known to use a placement device having a distal end shaped like an hourglass and a tapered, cone-shaped member to place the access device.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/  
Examiner, Art Unit 3767  
/Kevin C. Simons/  
Supervisory Patent Examiner, Art Unit 3767